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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/269,897

04/02/1999

KATSUMI AOYAGI

4047

1769

1109

7590

05/10/2006

ANDERSON, KILL & OLICK, P.C.  
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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/269,897	<b>Applicant(s)</b> AOYAGI ET AL.	
	<b>Examiner</b> Robert A. Zeman	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 4,11,12,34,37,38 and 41 is/are pending in the application.  
     4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,11,34,37,38 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-29-05</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The response filed on 2-8-2006 is acknowledged. Claims 4, 11-12, 34, 37-38 and 41 are pending. Claim 12 remains withdrawn from consideration. Claims 4, 11, 34, 37-38 and 41 are currently under examination.

### ***Information Disclosure Statement***

The Information Disclosure Statement filed on 8-29-2005 has been considered. An initialed copy is attached hereto.

### ***Declaration***

The declaration under 37 CFR 1.132 filed 2-8-2006 has been considered. It should be noted that the document identification number (present in the lower left hand corner) differs on page 4 of said declaration differs from those on pages 1-3 of said declaration.

### ***Claim Rejections Maintained***

### ***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting HCV in a

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biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "treatment solution" inactivates antibodies present in the sample and consists of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification), does not reasonably provide enablement for methods of detecting HCV utilizing treatment solutions or reaction buffers other than those set forth above or any methods for detecting HBV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims is maintained for reasons of record.

**Applicant argues:**

1. The Examiner admitted in a previous Office action (dated 7-25-2002) that the claimed method is effective in releasing the core antigens of both HCV and HBV but not for other viruses that is at odds with the aforementioned rejection.
2. The Declaration filed 2-8-2006 demonstrates that the specific composition of the reaction buffer is not essential to satisfy the requirements of enablement.
3. One of skill in the art would be able to determine to volume and composition of the reaction buffer to be used in the assay of HBV.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the claims to which the rejection of 7-25-2002 are not commensurate in scope with the instant claims. Hence, there is no "reversal" in the examiner's position.

With regard to Points 2 and 3, the Declaration is not found to be persuasive in that it does not address all the limitations of the claims (i.e. the conditions that inactivate endogenous antibodies but not the antibody probe). Additionally, the experiment set forth in the declaration does not utilize the same components differs from that set forth in the specification. (i.e. a treatment solution and reaction buffer was used). Additionally, Table 1 contradicts Applicant assertion that the procedures used in Example 5 were used. Example 5 used 5% SDS whereas the experiments set forth in the Declaration used 1.25% SDS. Additionally, the Declaration is silent as to the other components of the "Treatment". Moreover, finally, the experiments set forth in said Declaration set forth three possible "reaction buffers". This is not commensurate with the multitudes of possible "reaction buffers" encompassed by the instant claims. Finally, since the specification does not provide enablement for the detection of HCV, it cannot serve as the basis for enablement with regard to HBV.

As outlined previously, the instant claims are drawn to methods of detecting HCV or HBV in a biological sample by treating said sample with a "treatment solution" wherein said "treatment solution" inactivates antibodies present in the sample (see step 1 of claimed methods). Said sample is then subjected to an immunoassay that utilizes an antibody probe after the treated sample is added to a reaction buffer. The specification gives no guidance as to what combination of components, other than those set forth above, would result in a treatment solution that would inactivate the endogenous antibodies present in the biological sample (step 1 of the claimed methods) but not inactivate the antibody probe subsequently used in the immunoassay (step 2 of the claimed methods). Moreover, the specification is silent as to what, other than those components set forth on page 48 of the specification, constitute a "reaction buffer". The

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specification is equally silent on which antibody probes, if any, would be impervious to the inactivating properties of the claimed "treatment solution". Applicant has argued, "Applicant has been able to detect an antigen of HCV and HBV with a high degree of sensitivity". However, contrary to that assertion, only one working example (example 10) utilizes both a reaction solution and a reaction buffer. While the skill in the art of immunology, chemistry and protein chemistry is high, one of skill in the art would not be able to contemplate what combination of treatment solution components, reagent buffer components and antibody probe (other than those set forth above) would meet the limitations of the claimed methods since the antibody probe (which must remain functional in order to be used to detect viral antigens in the immunoassay) and the endogenous antibodies (which must be inactivated) are exposed to the identical conditions. Since, one of skill in the art would not readily be able to predict the effects of a given solution (i.e. that the solution inactivated the endogenous antibodies present in the sample but not inactivate any antibody probe), he/she would not be able to make the treatment solution or reaction buffer (other than those set forth above) needed to perform the claimed method without undue experimentation. Consequently, the specification is only enabling for methods of detecting HCV in a biological sample by treating said sample with a "treatment solution" and a "reaction buffer" wherein said "treatment solution" inactivates antibodies present in the sample and consists of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 and wherein the reaction buffer consists of 100 mM sodium phosphate buffer, pH 7.3, containing 0.15 M NaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1 M Tris (as defined on page 48 of the specification). It should be noted that the concentrations of solution components in HBV and HCV solutions differ (see Examples 4, 5, 6, 10 and 14). Moreover, the specification discloses no examples

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detecting HBV utilizing the combination of a "treatment solution" and a "reaction buffer". The only Example drawn to HBV utilizes a "treatment solution" only. Consequently, the specification is not enabling for any method of detecting HBV.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT ZEMAN  
PATENT EXAMINER

May 8, 2006